

Misbranding, Section 502 (a), the label statement "per cc. 0.22 mg. alpha Estradiol" was false and misleading as applied to the article, which contained less than 0.13 milligram of alpha estradiol per cubic centimeter.

DISPOSITION: July 30, 1948. Default decree of condemnation and destruction.

2466. Adulteration and misbranding of distilled water. U. S. v. Lincoln Laboratories, Inc. Plea of nolo contendere. Fine, \$750. (F. D. C. No. 23265. Sample Nos. 56546-H, 86728-H.)

INFORMATION FILED: December 18, 1947, Southern District of Illinois, against Lincoln Laboratories, Inc., Decatur, Ill.

ALLEGED SHIPMENT: On or about July 12, 1946, and May 9, 1947, from the State of Illinois into the State of Missouri.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Water for Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since it contained undissolved material which could be detected readily without magnification when examined in the manner described in the standard and since a portion of the article contained pyrogens and also was not sterile, but was contaminated with viable bacteria; and the difference in quality and purity of the article from the standard was not plainly stated, or stated at all, on its label.

Misbranding, Section 502 (a), the statement on the label of 1 shipment of the article "The contents of this vial consists of sterile, * * * pyrogen free water" was false and misleading, since the article involved in this shipment was not sterile but was contaminated with viable bacilli and contained pyrogens.

DISPOSITION: August 23, 1948. A plea of nolo contendere having been entered, the court imposed a fine of \$750.

2467. Adulteration of water for injection. U. S. v. 10 Boxes * * *. (F. D. C. No. 24886. Sample No. 4379-K.)

LIBEL FILED: June 14, 1948, District of Maine.

ALLEGED SHIPMENT: On or about April 21, 1948, by Brewer & Co., Inc., from Worcester, Mass.

PRODUCT: 10 boxes, each containing 25 ampuls, of *water for injection* at Portland, Maine.

LABEL, IN PART: "20-cc. Plus Water for Injection."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Water for Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since it was contaminated with undissolved material.

DISPOSITION: July 13, 1948. Default decree of condemnation and destruction.

2468. Adulteration and misbranding of peppermint leaves, belladonna leaves, and boneset. U. S. v. Allaire, Woodward & Co. and Norvin J. Busch. Pleas of nolo contendere. Fines of \$2,300 and costs against company and \$200 and costs against individual. (F. D. C. No. 24269. Sample Nos. 2443-K, 6415-K, 10275-K, 16817-K, 18026-K to 18028-K, incl., 18864-K, 19241-K, 19720-K, 27210-K.)

INFORMATION FILED: July 14, 1948, Southern District of Illinois, against Allaire, Woodward & Co., a corporation, Peoria, Ill., and Norvin J. Busch, president and treasurer.

ALLEGED SHIPMENT: Between the approximate dates of June 28, 1946, and December 18, 1947, from the State of Illinois into the States of West Virginia, New York, Wisconsin, Indiana, Ohio, and Missouri.

NATURE OF CHARGE: *Peppermint leaves*. Adulteration, Section 501 (d) (2), a product containing stramonium had been substituted for *peppermint leaves*. Misbranding, Section 502 (a), the label statements "Peppermint Leaves * * * it is Peppermint Leaves only" were false and misleading, since the article did not consist solely of *peppermint leaves* but also contained stramonium.

Boneset. Adulteration, Section 501 (d) (2), a product containing stramonium had been substituted for "Boneset * * * N. F." Misbranding, Sec-

tion 502 (a), the label statement "Boneset * * * N. F." was false and misleading, since the article did not consist of *boneset* which conformed to the requirements of the National Formulary.

Powdered belladonna leaf. Adulteration, Section 501 (d) (2), a product containing stramonium had been substituted for *belladonna leaf*. Misbranding, Section 502 (a), the label statement "Belladonna Leaf * * * U. S. P." was false and misleading, since the article did not consist of *belladonna leaf* which conformed to the requirements of the United States Pharmacopoeia, but did consist of a mixture of *belladonna leaf* and stramonium.

DISPOSITION: July 28, 1948. Pleas of nolo contendere having been entered, the court imposed fines of \$2,300 and costs against the corporation and \$200 and costs against the individual.

2469. Adulteration of wild cherry bark. U. S. v. 1 Bag * * *. (F. D. C. No. 24727. Sample No. 10531-K.)

LABEL FILED: April 16, 1948, District of New Jersey.

ALLEGED SHIPMENT: On or about December 15, 1947, by Ward G. Phillips, from North Wilkesboro, N. C.

PRODUCT: 1 bag of *wild cherry bark* at Jersey City, N. J.

LABEL, IN PART: "Thin Rossed Wild Cherry Bark."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Wild Cherry Bark," a drug the name of which is recognized in the National Formulary, an official compendium, and its quality and purity fell below the official standard since it was moldy and insect bored.

DISPOSITION: May 25, 1948. Default decree of condemnation and destruction.

2470. Adulteration and misbranding of prophylactics. U. S. v. 53 Gross * * *. (F. D. C. No. 24715. Sample No. 4025-K.)

LABEL FILED: April 8, 1948, District of Massachusetts.

ALLEGED SHIPMENT: On or about February 24, 1948, by the Duratex Corp., from Newark, N. J.

PRODUCT: 53 gross of *prophylactics* at Boston, Mass. Examination of samples showed that 2.1 percent were defective in that they contained holes.

LABEL, IN PART: "Arab Prophylactics Genuine Latex."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statement "Prophylactics" was false and misleading as applied to an article containing holes.

DISPOSITION: August 31, 1948. Default decree of condemnation and destruction.

2471. Adulteration and misbranding of prophylactics. U. S. v. 45 Gross * * *. (F. D. C. No. 25674. Sample No. 45622-K.)

LABEL FILED: September 28, 1948, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about August 25, 1948, by the World Merchandise Exchange & Trading Co., Inc., from New York, N. Y.

PRODUCT: 45 gross of *prophylactics* at St. Louis, Mo. Examination of samples showed that 7.4 percent were defective in that they contained holes.

LABEL, IN PART: "Tetratex Manufactured By L. E. Shunk Latex Prod. Inc., Akron, Ohio."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statements "Prophylactic," "Prophylactics * * * has been electronically tested and hermetically sealed in metal for your protection," and "Electronically Tested * * * hermetically sealed in individual metal containers for your protection" were false and misleading as applied to an article containing holes.

DISPOSITION: October 22, 1948. Default decree of condemnation and destruction.

2472. Adulteration and misbranding of prophylactics. U. S. v. 43 Dozen * * *. (F. D. C. No. 24486. Sample No. 21169-K.)

LABEL FILED: March 16, 1948, Western District of Missouri.